



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 2, 2016

Biomet, Incorporated
Ms. Patricia S. Beres
Senior Regulatory Specialist
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581

Re: K080642

Trade/Device Name: Comprehensive® Reverse Shoulder
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS
Dated: June 25, 2008
Received: June 27, 2008

Dear Ms. Beres:

This letter corrects our substantially equivalent letter of July 9, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080642

Device Name: Comprehensive® Reverse Shoulder

Indications For Use:

The Comprehensive® Reverse Shoulder is indicated for use in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary.

The Comprehensive® Reverse Shoulder is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.

Glenoid components with Hydroxyapatite (HA) coating applied over the porous coating are indicated only for uncemented biological fixation applications. The Glenoid Baseplate components are intended for cementless application with the addition of screw fixation.

Interlok® finish humeral stems are intended for cemented use and the MacroBond® coated humeral stems are intended for press-fit or cemented applications. Humeral components with porous coated surface coating are indicated for either cemented or uncemented biological fixation applications.


Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use NO
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

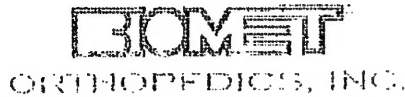
Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K080642

K080642



JUL - 9 2008

510(k) Summary - K080642

Preparation Date: July 7, 2008

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: Comprehensive® Reverse Shoulder

Common Name: Shoulder Prosthesis

Classification Name: Shoulder joint, metal/polymer, semi-constrained, cemented prosthesis (21 CFR 888.3660)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Comprehensive® RS Shoulder	Biomet, Inc.	K072804
Anatomical Shoulder™ Inverse/Reverse	Zimmer, Inc.	K053274
Equinoxe® Reverse Shoulder System	Exactech	K063569, K073688
Encore Reverse Shoulder Prosthesis	Encore Medical	K041066, K051075
Trabecular Metal™ Reverse Shoulder	Zimmer, Inc.	K052906

Device Description: The Comprehensive® Reverse Shoulder is intended for total shoulder replacement in a reverse shoulder configuration. Unlike traditional total shoulder replacement, a reverse shoulder employs a ball for articulation on the glenoid side of the joint and a polyethylene bearing surface on the humeral side of the joint. The components may be used as a primary procedure or during the revision of a failed shoulder prosthesis.

For a reverse shoulder application, a Glenosphere Baseplate with a Glenosphere is implanted into the glenoid side of the joint. The Glenoid Baseplate is attached to the natural bone with the use of a Central Screw and Peripheral Screws. A Humeral Tray with a Humeral Bearing is attached to a Comprehensive® Humeral Stem to complete the humeral side of the joint. The use of a standard Comprehensive® humeral component provides the surgeon with the option of leaving a well-fixed humeral stem from a previous total or hemi-shoulder surgery in place while still being able to convert the shoulder to a reverse configuration. It also would facilitate the conversion of a reverse configured shoulder to a hemi-shoulder in the future if the need were to arise.

Mailing Address:
Biomet
One Biomet Drive
Warsaw, IN 46583-0001
Phone: (317) 926-7000
Fax: (317) 926-7001
E-Mail: info@biomet.com

Shipping Address:
Biomet
One Biomet Drive
Warsaw, IN 46583

Intended Use: Biomet Comprehensive® Reverse Shoulder products are indicated for use in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary.

The Comprehensive® Reverse Shoulder is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.

Glenoid components with Hydroxyapatite (HA) coating applied over the porous coating are indicated only for uncemented biological fixation applications. The Glenoid Baseplate components are intended for cementless application with the addition of screw fixation.

Interlok® finish humeral stems are intended for cemented use and the MacroBond® coated humeral stems are intended for press-fit or cemented applications. Humeral components with porous coated surface coating are indicated for either cemented or uncemented biological fixation applications.

Summary of Technologies: The Comprehensive® Reverse Shoulder has similar technologies as the predicate devices.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

*All trademarks of property of Biomet, Inc. except for the following:
Anatomical Shoulder is a trademark of Zimmer GMBH
Trabecular Metal is a trademark of Zimmer Trabecular Metal Technology, Inc.
Equinox is a trademark of Exactech, Inc.*